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10/511,265	10/19/2004	Andrea Trombi	024931-00027	6283

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EXAMINER

MATTER, KRISTEN CLARETTE

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3771

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,265	Applicant(s) TROMBI, ANDREA	
	Examiner Kristen C. Matter	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/19/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

In the present case, the oath or declaration filed on 4/18/2005 is assumed to have been filed to replace the oath or declaration filed on 10/19/2004. However, the later filed oath or declaration omits the priority information of the claimed PCT application ((PCT/IT02/00680) filed on 10/25/2002.

Specification

The abstract of the disclosure is objected to because use of the term "comprising" on line 2 and "comprises" on line 6 is considered claim language. Correction is required. See MPEP § 608.01(b). Examiner suggests changing "comprising" to --including-- on line 2 and "comprises" to --includes-- on line 6.

Drawings

The drawings are objected to because of the following informalities:

The shading in Figure 3 makes it difficult to see the details of the drawing and should be removed;

Multiple reference characters throughout the drawings are illegible and need to be rewritten clearly or typed in;

In Figure 1, reference characters A, B, and C should be replaced with numerals.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: line A-A in Figure 2.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the channel must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 1 is objected to because of the following informalities: on lines 13-14, use of the language “called primary flow” and “called secondary flow” is somewhat confusing. Examiner suggests replacing “injecting a flow of air, called primary flow” and “introducing a flow of air, called secondary flow” with --injecting a primary flow of air-- and --introducing a secondary flow of air--, respectively. Also, Examiner suggests changing “a supplementary, or secondary, channel” to --a secondary channel-- to remain consistent with the rest of the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 3, 6, 7, 8, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, use of the language, “at least” throughout the claim makes it confusing as to what all is actually required for the invention. Examiner suggests deleting all instances of “at least” in the claim.

Regarding claims 1 and 11, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation "below an outlet (6a) of the distributor element (4)", and the claim also recites "or in any case below a plane of generation of the nebulisation" which is the narrower statement of the range/limitation.

Claims 2, 3, 6, and 7 are dependent on claim 1 and are therefore rejected for the reasons outlined above with respect to claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 6, 7, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kremer, Jr. et al. (US 4,792,097) (herein referred to as Kremer).

Regarding claims 1 and 11, Kremer discloses a nebulizer apparatus with a nebulizer ampoule for therapeutic applications comprising a mouthpiece (column 4, lines 54-55), a distributing element (22) physically separate from an activation element (48' or 30) capable of activating nebulization (or at a minimum further breaking up particles), the distribution element comprising a nozzle (19), a coating body (26) inserted on the nozzle and forming a channel (25) for conveying a medical product from a tank (14) to a nebulization area, and a secondary channel (29 or 44) for refining the nebulization of the product with portions (38 or the small extension seen at reference character 41 on Figure 2) defining extensions of lateral walls (37 or 29) of the secondary channel. Please note that Examiner believes there are two separate channels and activation elements in the Kremer reference that read on the present invention.

Regarding claim 2, the portions (38) consist of a ring connected to the coating body by supporting elements (42) positioned at the lower ends of the lateral walls (see Figure 2). Kremer further discloses that larger particles strike the walls of the portions (38) and are returned to the tank (column 4, lines 15-20). Alternately, the area above reference character 30 in Figure 2 can be considered a supporting member.

Regarding claim 3, regardless of whether wall 30 or wall 48' are considered the activation element, one can clearly see from the figures that the elements are circular in cross section with flat ends (i.e., 48' is horizontal and 30 is flat at a 45 degree angle), and are a pre-set distance from the outlet of the nozzle.

Regarding claim 6, the secondary channel is co-axial to the distributor element (see Figure 2).

Regarding claim 7, wall 30 is made as a single piece with secondary channel 29 and wall 48' is made as a single piece with secondary channel 44 (see Figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer. Examiner believes that the walls of the secondary channel (29 or 44) as seen in Figure 2 extend below the plane of nebulization (which occurs at both 30 and 48' to some extent), but to the extent, if any, that this is not the case Kremer discloses that the wall can extend downwardly towards the bottom wall a considerable distance further than shown (column 3, lines 30-35). It is considered an obvious design consideration to one of ordinary skill in the art to extend this wall below the outlet of the distributor element of at least below a plane of nebulization to better control the flow of nebulized product.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blacker et al. and Piper are cited to show other similar nebulizers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen C. Matter
Examiner
Art Unit 3771



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6/7/07